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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/643,686	08/24/2000	Gerald Quapil	31833-150836 (RK)	2565
26694	7590	06/15/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			PADMANABHAN, KARTIC	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/643,686	Applicant(s) QUAPIL ET AL.	
	Examiner Kartic Padmanabhan	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-19 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-19, 22, 23 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 2-19 and 22-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-19, 22-23, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lekkala et al. (WO 95/22754) in view of Babson et al. (US Pat. 5,885,530).

Lekkala et al. teach a device for carrying out analysis, comprising an analysis well for receiving the substance to be analyzed, a light source (5), and a detector (6). The bottom of the reaction space is coated with a layer of material that can generate an SPR signal. The bottom part of the analysis well is transparent to light. The device also comprises a prism boundary surfaces for the emerging light, as well as for total reflection. The light source is directed through the prism towards the reaction space, wherein the detector is arranged such that it receives light from the prism (abstract). The well of the reference has side walls at angles of less than 90 degrees, as seen in the Figures. Further, since the vessel is in the form of a well, it is inherent from the figures that it is a hollow-cylindrical shape with cylindrical bases. The wells of the reference may be in the form of several wells arranged in a row or matrix. The wells can also be arranged in succession in a strip made of plastic in which there are several adjacent wells. These strips can be placed side by side to form the structure of a microtiter plate, such that the strips of wells can be inserted into a housing that holds all the strips to create a microtiter plate structure. The bottoms of the strips can have the shape of any of the prisms (page 5, lines 9-21). The well may specifically be made of polystyrene (page 2, lines 24-25). The measurement of the reference is performed such that a polarized light beam is incident through the prism, and light is totally reflected back into the prism at the boundary surface (page 3, lines 12-35). The light source of the reference may be a laser or LED. The device of the reference further comprises collimating optics and focusing optics (page 4, lines 26-36). When strips of wells are used, the device can comprise a row of light sources and a two-dimensional detector of several detectors as the CCD detector (page 6, lines 10-17). The light must be polarized, such that if the light source does not have its own polarizer, one can be placed between the light source and the prism

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(page 6, lines 25-28). The well plates and strips of the reference can be fabricated by spray molding using plastic material. Further, instead of assembling separate strips, the plate can be made by molding from a single piece (page 7, lines 3-12). However, the reference does not teach a common receiver.

Babson et al. teach an automated immunoassay analyzer comprising a plurality of reaction tubes in which assays can be performed. The detector (receiver) of the device is a photomultiplier tube that receives the signal from all the reaction tubes.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the photomultiplier tube of Babson et al. with the device of Lekkala et al. because photomultipliers and CCD are both commonly used as detectors in optical immunoassays. Further, the use of one central receiver, as opposed to multiple receivers, has the advantage of being more cost-effective and convenient. Further, the use of one receiver eliminates systemic variation between receivers that may distort assay results. In addition, it has been held that omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184. As applied to this case, the omission of multiple receivers would have been obvious because the use of a single common receiver would still perform the same function of receiving the signal, and one of skill in the art would have known how to adapt such a receiver to receive signals from multiple vessels.

Response to Arguments

5. Applicant's arguments filed 5/10/04 have been fully considered but they are not persuasive.

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6. Applicant first argues that both Lekkala and Babson teach only one transmitter and one receiver. This assertion is erroneous. Lekkala clearly teaches multiple transmitters and receivers (See 35 USC 013 rejection above). In fact, applicant, in page 8 of their response of 11/12/03, states that “[a]s shown in Figures 4a and 4b of Lekkala, and also described on page 6, the transmitters are assigned several receivers or receiving elements by a CCD line” (emphasis added by applicants). Further, applicant only specifically addresses Babson in reference to the number of transmitters and receivers, while only making a general conclusion in reference to Lekkala, which conclusion is in error.

7. In terms of Babson, the examiner acquiesces that the reference only consists of one transmitter; however, Lekkala was relied upon for teaching multiple transmitters and reaction wells, and Babson was only relied upon for teaching a single receiver. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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9. Applicant's argument that the combination of references fails to teach the synchronization of transmitters, such that "the transmitters successively emit light rays which can be successively evaluated by the receiver," *may* indeed be accurate. However, this position is immaterial to the issue of patentability in a device claim, as they are method limitations. Process steps do not merit patentable weight in a claim drawn to a device.

Conclusion

Claims 2-19, 22-23, and 27 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/10/04